Joseph R. Saveri (State Bar No. 130064)
Steven N. Williams (State Bar No. 175489)
Nicomedes Sy Herrera (State Bar No. 275332)
Kevin Rayhill (State Bar No. 267496)
Anupama K. Reddy (State Bar No. 324873)
JOSEPH SAVERI LAW FIRM, INC.
601 California Street, Suite 1000
San Francisco, California 94108
Telephone: (415) 500-6800
Facsimile: (415) 395-9940
Email: jsaveri@saverilawfirm.com
swilliams@saverilawfirm.com
nherrera@saverilawfirm.com
krayhill@saverilawfirm.com
asatyasai@saverilawfirm.com

Attorneys for Plaintiff-Relator Zachary Silbersher

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA; STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, AND WASHINGTON; THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA; AND THE DISTRICT OF COLUMBIA,

ex rel. ZACHARY SILBERSHER,

Plaintiffs,

v.

JANSSEN BIOTECH, INC., JANSSEN ONCOLOGY, INC., JANSSEN RESEARCH & DEVELOPMENT, LLC, and JOHNSON & JOHNSON,

Defendants.

Case No.3:17-cv-07250-JST

PLAINTIFF-RELATOR'S OPPOSITION TO DEFENDANTS' MOTION TO DISMISS (DKT. 32)

Judge: Hon. Jon S. Tigar

Date: May 16, 2019

Time: 2:00 p.m.

Place: Courtroom 9, 19th Floor, Phillip Burton Federal Building

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I. INTRODUCTION

The Amended Complaint (Dkt. 7) (the "Complaint") alleges that Defendants caused the submission of false claims for payment of their drug, Zytiga, to government-funded health programs. Defendants[1] made false representations to the United States Patent and Trademark Office ("USPTO") to obtain a patent used to unlawfully exclude competitors and maintain monopoly prices for Zytiga. Therefore, every claim for payment submitted to a government-funded health program for Zytiga that included an inflated price was a false claim under the False Claims Act, 31 U.S.C. §§ 3729–3733 (the "FCA"). To qualify Zytiga for payment from government health programs, Defendants also listed Zytiga on the Federal Supply Schedule ("FSS") pursuant to General Services Administration ("GSA") regulations. Defendants were required to and did make express and implied representations to the government that Zytiga's prices were "fair and reasonable."

Defendants knew the pricing was not "fair and reasonable" because Defendants artificially inflated those prices with a patent procured by fraud. Therefore, every claim for Zytiga from such government health programs violated the FCA as a fraudulently-induced claim under *U.S.* ex rel. *Campie v. Gilead Scis., Inc.*, 862 F.3d 890 (9th Cir. 2017). Finally, but for Defendants' unlawful exclusion of competitors, approximately 90% of Zytiga prescriptions would have been filled with a lower-cost generic alternative. Every claim relating to a Zytiga prescription that would have been substituted for a generic version also violated the FCA.

Plaintiff-Relator Zachary Silbersher ("Relator"), a patent attorney, discovered Defendants' fraudulent scheme. He discovered it not from any public source, but through his expertise and investigation. Defendants attempt to dismiss Relator because he is not a traditional "insider." Nowhere does the FCA require a relator to be an insider, and such an arbitrary requirement would defeat the FCA's goal of protecting the public fisc from fraud. Indeed, Congress amended the FCA, as part of the Affordable Care Act in 2010, specifically to permit suits such as the one Mr. Silbersher brings, so that

[1] Defendants Janssen Biotech, Inc., Janssen Oncology, Inc., and Janssen Research & Development, LLC filed certifications that they all were real parties-in-interest for the '438 Patent, and that all of them were wholly-owned subsidiaries of defendant Johnson & Johnson ("J&J"). *See, e.g., BTG Int'l Ltd., Janssen Biotech, Inc., Janssen Oncology, Inc., and Janssen Research & Dev., LLC v. Amneal Pharms. LLC, et al.*, No. 19-1147, Dkt. 77, at i (Fed. Cir. Dec. 3, 2018).

private citizens who are not traditional insiders with direct knowledge can "come forward to expose fraud, which is a crucial way to save the government money and ensure the health and well-being of Americans." *See* 155 Cong. Rec. S13661-95 (2009), at S13693. In particular, Congress removed the requirement that a relator needs to have "direct" knowledge of fraud to be an "original source." Congress also permitted relators to bring suits based on facts that had already been previously alleged and disclosed in criminal, civil, or administrative proceedings, so long as the federal government was not a party. *See id.*; PL 111-148, March 23, 2010, 124 Stat 119; 31 U.S.C. § 3730(e)(4). Mr. Silbersher is a proper relator under the FCA.

Defendants argue that Relator has failed to allege a "false or fraudulent claim." This ignores the detailed, well-pleaded allegations of the Complaint. Relator alleges sufficient factual detail with respect to each element of an FCA claim. Moreover, the Complaint's allegations compare favorably to those upheld in recent Supreme Court and Ninth Circuit cases. *See e.g., Universal Health Servs., Inc. v. United States* ex rel. *Escobar,* _U.S._, 136 S. Ct. 1989 (2016); *Campie*, 862 F.3d 890. Defendants also claim that Relator failed to plead fraud with particularity under Rule 9(b). This also is wrong. The detailed allegations in the complaint specify the date, documents, details, responsible parties, and recipients of Defendants' misrepresentations. The Complaint also sufficiently alleges Defendants' scienter and describes why Defendants' misrepresentations were material.

Defendants assert that their false statements lack a proper nexus to any false claim because the causal chain is too attenuated. Defendants say that any false statements they made were not explicitly included in Zytiga claims, but rather were made to government agencies not directly responsible for paying them. These assertions are at odds with the Complaint. At most, they raise factual issues not to be resolved on a motion to dismiss. All claims for payment of Zytiga included an inflated price that Defendants were able to charge by unlawfully excluding competitors. As the Complaint alleges, the purpose for which Defendants fraudulently obtained the '438 Patent was to exclude competitors so that Defendants could continue charging supracompetitive prices. The inflated prices not only were the foreseeable result of Defendants' misconduct, they were its particular purpose. Finally, the Ninth Circuit long ago settled that a defendant is liable under the FCA so long as the defendant's false statements are an essential part of a causal chain leading to payment, regardless of the layer of the bureaucracy to which the

false statements were directed. *Campie*, 862 F.3d at 896 (collecting cases); *U.S. ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1174 (9th Cir. 2006). Defendants' misleading statements to the USPTO in obtaining the '438 Patent, and Defendants' false certifications to the GSA concerning Zytiga's "fair and reasonable" pricing, give rise to FCA liability.

Defendants contend the Complaint should be dismissed under the "public disclosure" bar, but they fail to identify a single document that discloses the central elements of the fraud alleged in the complaint. Through his independent investigation, Relator uncovered that Defendants obtained the '438 Patent through fraud. Much of that investigation, and the allegations of fraud here, were not disclosed in the *Inter Partes* Reviews ("IPRs") (upon which Defendants primarily rely). Nevertheless, even if all the elements of Defendants' fraud were publicly disclosed—and they were not—Relator may proceed because he is an "original source" and added material information to the scant, publicly-available information.

II. STATEMENT OF FACTS

A. Background

Defendants manufacture, sell, and distribute Zytiga® (abiraterone acetate), a branded drug which is prescribed for metastatic castration-resistant prostate cancer ("mCRPC"). Zytiga costs approximately $9,000 per month and generates $2 billion in annual revenue for J&J and the related Janssen entities. J&J derives most of its Zytiga income through payments by government health funds. (Complaint, ¶¶ 2-3) Approximately 80% of prostate cancer patients in the United States are covered by Medicare, and the Plaintiff States' Medicaid programs also cover Zytiga. (*Id.*, § 3) Additionally, the federal government purchases Zytiga through numerous programs, including the Veterans Health Administration. *Id.*

The Complaint alleges[2] that Defendants fraudulently obtained U.S. Patent 8,822,438 ("the '438 Patent") to exclude generic competitors from offering a lower-priced generic alternative to Zytiga, thereby inflating the price by 650%. (*Id.*, ¶ 54) In particular, Defendants—through their agents—fraudulently obtained the '438 Patent by knowingly making material misrepresentations to the USPTO in prosecuting

[2] The Ninth Circuit has instructed that the scope of false or fraudulent claims should be broadly construed . . . ." *Hendow*, 461 F.3d at 1171. In broadly applying the FCA, the Court should accept all alleged facts to be true and draw all reasonable inferences in Relator's favor. *Usher v. City of Los Angeles,* 828 F.2d 556, 561 (9th Cir. 1987).

the patent application. *See* § II.B, *infra*. They did so in direct contravention of the statutory duty of "candor and good faith" to the USPTO under 37 C.F.R. § 1.56, which is imputed on Defendants as the principals and real parties-in-interest to the '438 Patent. (Complaint, ¶¶ 53, 64, 67-77) The duty of "candor and good faith" is critical, because patent prosecutions are *ex parte,* non-adversarial proceedings. The USPTO relies on parties prosecuting a patent—including the real parties-in-interest—to provide patent examiners with all material information necessary to fairly determine patentability, particularly if such information would have a tendency to refute patentability. *See* Manual of Patent Examining Procedure, § 2001.04*; see also* Complaint ¶¶ 53, 64.

To receive payment for Zytiga from various government health programs, Defendants were required to list Zytiga on the Federal Supply Schedule ("FSS"). In doing so, Defendants expressly and impliedly certified that Zytiga prices were "fair and reasonable." *See* 48 C.F.R. §§ 8.404(d); 15.402(a) (2018). As Relator alleges, Defendants knew the prices of Zytiga were not "fair and reasonable" because Defendants artificially inflated by unlawfully eliminating price competition through fraud. (*Id.*, ¶¶ 104-112). As a result of Defendants' false certifications, tens of thousands of false claims seeking payment for Zytiga at an unlawfully inflated price were submitted to, and paid by, the federal government and the Plaintiff States.

B. Defendants Unlawfully Excluded Competitors Through the Fraudulent '438 Patent

The '438 Patent covers administration of abiraterone in combination with the steroid prednisone. (Complaint, ¶ 67; Defendants' Request for Judicial Notice ("RJN"), Dkt. 33, Ex. B ('438 Patent col. 16:15-20)) Defendants' application for the '438 Patent (Application No. 13/034,340, "the '340 Application"), was rejected by the USPTO at least three times because the claimed invention—administration of abiraterone with prednisone—was obvious in light of prior art. Defendants attempted to rebut USPTO's rejections by arguing that Zytiga's commercial success was evidence of a secondary consideration.[3] However, the patent examiner again rejected the patent because Defendants had not

[3] Pursuant to the Patent Office's Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103, an applicant may submit "objective evidence relevant to the issue of obviousness . . . , sometimes referred to as 'secondary considerations,' [which] may include evidence of commercial success, long-felt but unsolved needs, failure of others, and unexpected results."

shown that Zytiga successfully captured market share against competing mCRPC treatments. (Complaint, ¶ 67-74)

In response, Defendants made fraudulent and misleading statements to the USPTO concerning Zytiga's purported market share success. For example, Defendants falsely claimed that Zytiga had gained significant market share in the market for chemo-naïve (*i.e.*, patients who have not received chemotherapy) mCRPC patients against Xtandi® and bicalutamide. (*Id.*, ¶¶ 75-82) As the Complaint alleges, Xtandi had yet to obtain FDA approval for the chemo-naïve market during the time specified by Defendants. In violation of their duty of candor and good faith, Defendants failed to disclose this critical fact. (*Id.,* ¶ 77(a)-(d)) In the same submission, Defendants justified Zytiga's own poor market share against other mCRPC indications by emphasizing that Zytiga had yet to obtain FDA approval for that indication. (*Id.,* ¶ 77(d)) This demonstrated that Defendants knew FDA approval was material to market success for a given indication. These allegations sufficiently plead materiality and scienter. *See infra* at §§ III.A.4 & 5.

Defendants also failed to disclose that Zytiga's commercial success directly resulted from a blocking patent ("the '213 Patent'"), which expired in December 2016, that deterred competitors from introducing generic abiraterone acetate prior to that date. (*Id.,* ¶ 80(e)) Indeed, this was one of the reasons the USPTO's Patent Trial and Appeal Board ("PTAB") invalidated the '438 Patent in several *inter partes* reviews of the '438 Patent filed by generic manufacturers. *See Amerigen Pharms., Ltd. v. Janssen Oncology, Inc.*, Case IPR2016-00286 (collectively, the "IPRs").[4]

Defendants asserted their fraudulently-acquired '438 Patent in several objectively baseless infringement actions to prevent generic manufacturers from entering the market. (*Id.,* ¶ 90) By filing the infringement lawsuits, Defendants triggered a 30-month stay on FDA approval of the Abbreviated New Drug Applications ("ANDAs") filed by generic manufacturers seeking to enter the market. (Complaint, ¶¶ 90, 94) The generic manufacturers have been ready to enter the market since December 2016, but they have been prevented from doing so because of Defendants' fraudulent scheme. (*Id.*, ¶¶ 85-93).

[4] *Inter partes* review is a proceeding conducted at the PTAB to review the patentability of one or more claims in a patent only on a ground that could be raised under 35 U.S.C. §§ 102 or 103, and only on the basis of prior art consisting of patents or printed publications.

Defendants used their fraudulently-obtained '438 Patent to exclude generic competition and charge an artificially high price for Zytiga. (*Id.*, ¶¶ 58, 88-91) But for Defendants' fraudulent scheme, generic competition would have reduced the price of the drug by at least 85%, and Defendants would have lost 90% of Zytiga's market share. (*Id.,* ¶ 54)

C. Defendants Submitted or Caused the Submission of False Claims

Zytiga—which costs almost $9,000 per month in the absence of generic competition—generates approximately $2 billion per year for Defendants. (*Id.,* ¶ 3, 13; RJN, Ex. HH) Much of this revenue is derived from federal health programs. Each claim for payment or reimbursement from a government health care program constitutes a false claim in violation of the FCA and the state FCA of the respective states. Those claims are false because they charged an artificially inflated price that Defendants maintained by unlawfully excluding generic competitors. (Complaint ¶¶ 94-103).

Moreover, the prices the government paid or reimbursed for Zytiga were calculated on prices Defendants explicitly and impliedly certified were "fair and reasonable" in accordance with basic principles underlying the Federal Acquisition Regulations. (*Id.,* ¶¶ 104-116). Zytiga would have been ineligible for payment under government health programs but for Defendants' false certification of "fair and reasonable" prices. Therefore, every claim seeking payment for Zytiga from such government health programs constituted a false claim under the FCA. *See Campie*, 862 F.3d at 902 (FCA "liability will attach to each claim submitted to the government under a contract, when the contract or extension of the government benefit was originally obtained through false statements or fraudulent conduct").

Relator filed this action on December 21, 2017. Thereafter, in January 2018, the PTAB invalidated the '438 Patent. *See, e.g., Amerigen Pharm. Ltd. v. Janssen Oncology, Inc.*, IPR2016-00286 (P.T.A.B. Jan. 17, 2018). Defendants are appealing the IPRs and district court decisions invalidating the '438 Patent in a consolidated appeal, Nos. 19-1147, 19-1148, 19-1168, and 19-1236.

III. ARGUMENT

A. Relator Has Adequately Alleged Facts to State Claims Under the FCA

To allege an FCA claim, Relator must plead: "(1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, causing (4) the government to pay out money or

forfeit moneys due." *Campie*, 862 F.3d at 899.

The FCA is a remedial statute that should be broadly construed. Congress has revised the FCA on two occasions to make it easier for relators to bring *qui tam* actions. According to the Ninth Circuit, the FCA is "intended to reach all types of fraud, without qualification, that might result in financial loss to the Government." *U.S.* ex rel. *Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1170–71 (9th Cir. 2006); *see also Campie*, ("We construe the Act broadly").

1. The FCA Does Not Require That a Relator be an "Insider"

Congress amended the FCA in 2010 specifically to open the way for suits such as this, where private citizens who are not traditional "insiders" can "come forward to expose fraud, which is a crucial way to save the government money and ensure the health and well-being of Americans." *See* 155 Cong. Rec. S13661-95 (2009), at S13693. As long as the other provisions of the FCA are met, there is no limitation that disqualifies Relator.

Particularly for healthcare fraud involving pharmaceutical patents, a relator such Mr. Silbersher should not be discouraged. Pharmaceutical patents are complex. Because of the large amounts of money paid for pharmaceuticals, there is an enormous incentive for fraudulent or anticompetitive activity.[5] The exclusion of generic competition, like other healthcare abuse, places enormous costs on society, including the government. Litigation challenging these practices is frequently, as here, conducted out of public view. In this case, Defendants' fraud remained hidden for years, known only to Defendants' patent prosecution and business personnel who misled USPTO to obtain the '438 Patent. They did so to protect Zytiga from legitimate competition. It took a great deal of technical, scientific, and legal expertise to unravel and expose Defendants' fraudulent scheme. Identifying such fraud is not reasonably ascertainable to the U.S. government when they reimburse the cost of pharmaceuticals. It takes someone with Mr. Silbersher's particular expertise to uncover such fraud and bring it to light. This is a basic premise of the FCA. *Id.*

[5] Defendants point out that Relator has filed at least three other suits alleging similar FCA claims based on fraudulent patents. As the allegations in these suits show, pharmaceutical companies exploit the *ex parte* nature of patent prosecution and ignore their statutory duties of candor and good faith, knowing that even if fraudulently obtained patents are later challenged and invalidated, they can extend drug monopolies for years and continue reaping supracompetitive profits while validity is litigated. Robust enforcement is necessary to stem a clear pattern of fraudulently-acquired patents propping up high drug prices.

2. Defendants' Fraud Violates the Plain Language of the FCA

Relator pleads facts sufficient to state a claim under the FCA in several ways.

First, every claim for payment submitted to a government-funded health program for Zytiga that included an inflated price based on Defendants' unlawful exclusion of generic competitors was a false claim. *See* 31 U.S.C. § 3729(a)(1)(A) (any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" violates the FCA). (Complaint ¶¶ 9, 94-98, 102)

Second, Defendants provided explicit and implied representations to the government that the price of Zytiga was "fair and reasonable." (Complaint ¶¶ 104-116) Yet, as Defendants knew, the price of Zytiga was *not* fair and reasonable because they unlawfully excluded generic competition based upon a fraudulent patent. (*Id.*, ¶¶ 106, 110-116) Thus, each claim submitted to such government health programs for payment for Zytiga constituted a false claim under the fraudulent inducement doctrine.[6] This is because Zytiga's eligibility to receive government health funds was "originally obtained through false statements or fraudulent conduct" that led to Zytiga's listing in the FSS for nearly $9,000 for a one-month prescription, when the fair and reasonable price (absent Defendants' unlawful exclusion of competitors) would have been only $900 to $1,350. (*Id.*, ¶ 54) *See Campie*, 862 F.3d at 902; *Hendow*, 461 F.3d at 1173.

Third, many states require or permit pharmacists to substitute an available generic unless the prescription specifically requires that a brand drug be dispensed. (Complaint ¶¶ 56, 99) But for Defendants' misrepresentations, approximately 90% or more of the Zytiga subscriptions paid or reimbursed through government health programs would have instead been for significantly lower-priced generic Zytiga. (*Id.*¶¶ 56, 99, 101) Each claim for payment or reimbursement for Zytiga that would have been substituted for a less expensive generic equivalent constituted a false claim. *See, e.g.,* 31 U.S.C. § 3729(a)(1)(A). Courts uniformly hold that drug prescriptions procured through anti-competitive conduct, such as through unlawful kickbacks, constitute "false and fraudulent" claims under the FCA.

[6] Under either the "false certification theory or the promissory fraud theory, the essential elements of FCA liability remain the same . . . ." *Hendow*, 461 F.3d at 1174.

See, e.g., U.S., ex rel. *Solis v. Millennium Pharm., Inc.*, No. 2:09-CV-03010-MCE, 2015 WL 1469166, at *6 (E.D. Cal. Mar. 30, 2015).

Fourth, Defendants fraudulently obtained the '438 Patent through misrepresentations and omissions of material fact to the USPTO in violation of the affirmative duties of good faith and candor. (Complaint, ¶¶ 75-81) Those misrepresentations and omissions constituted "false records or statements material to a false or fraudulent claim" for Zytiga. 31 U.S.C. § 3729(a)(1)(B).

3. The Sufficiency of Relator's Allegations is Confirmed by Recent Supreme Court and Ninth Circuit Precedent

The sufficiency of Relator's allegations is confirmed by recent caselaw construing the FCA. In *Escobar,* 136 S. Ct. 1989, the Relator alleged that claims submitted to Medicaid for counseling services were "false and fraudulent" under the FCA when the claims referred to billing codes corresponding to services such as "family therapy" and job titles such as "Social Worker, Clinical." *Id.* at 1997. The Supreme Court held that such claims violated the FCA because the social workers were unlicensed under state law—even though neither the claims nor the billing code descriptions contained an explicit representation the social workers were "licensed" under state law. Focusing on the plain meaning of the FCA and eschewing a "circumscribed" interpretation, the Court held the claims defrauded the government because such qualifications were *implied*. *Id.* at 1997-98 & 2000.

Like in *Escobar*, the fraud that Relator alleges in the Complaint satisfies the plain meaning of the FCA. (Complaint, ¶¶ 75-99; 100-116). Moreover, the facts alleged here present a stronger case for FCA violations than those asserted in *Escobar* because, as Relator specifically alleges, Defendants made express *and* implied representations that Zytiga's price was "fair and reasonable" when it was not. (*Id.*, ¶¶ 5, 60-74, 117-130) Moreover, Defendants' fraud here resulted in the government paying highly inflated drug prices, which directly drains public funds as compared with the implied false certification in *Escobar*.

In *Campie*, the Ninth Circuit reversed the dismissal of an FCA complaint alleging that Gilead obtained FDA approval of its drugs through false statements to the FDA. Foreign manufacturing locations must register with the FDA before drugs made in those locations can be imported into the U.S. The *Campie* relators alleged that Gilead manufactured its drugs in unregistered locations, which relators

claimed made them ineligible for payment. *Id.,* 862 F.3d at 896. The court rejected Gilead's arguments—also made by Defendants here—that the fraud lacked a sufficient nexus to the claim for payment because the misrepresentations were made to the FDA, and not directly to the paying agencies. *Id.* at 903. So long as a defendant's false statements are an essential part of a causal chain leading to payment, Defendants are liable under the FCA. *Id. See also Hendow*, 461 F.3d at 1174 ("the precise logistical details of how the claim is made—with respect to timing, for instance, or the number of stages involved—are immaterial: '[i]f a false statement is integral to a causal chain leading to payment, it is irrelevant how the federal bureaucracy has apportioned the statements among layers of paperwork.'") (internal citation omitted).

Relator's claims here present an even stronger case under the FCA than those in *Campie*. In *Campie*, there was no allegation that the invoices for Gilead's drugs mentioned *anything* concerning the location where the drugs were manufactured. The court did not even require proof that the drugs were worthless or unusable, or that the government paid too much compared with the drug's intrinsic economic value. *Id.* at 900. Here, the claims for payment specifically included prices Defendants represented were fair and reasonable, and the government was actually overcharged by 650% or more. (Complaint, ¶ 73, 131-144) At the very least, Relator's allegations raise an issue of fact.

4. Relator Sufficiently Pleads Materiality

Under the FCA, a falsehood is material if it has the "natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4); *Campie*, 862 F.3d at 904-05. *Escobar* and its progeny confirm that the Complaint's allegations are sufficient.

Upon remand, the First Circuit in *Escobar* held that the "centrality" of the regulations that defendants violated was "strong evidence that a failure to comply with the regulations would be 'sufficiently important to influence the behavior' of the government in deciding whether to pay the claims." *See U.S.* ex rel. *Escobar v. Universal Health Servs., Inc.,* 842 F.3d 103, 111 (1st Cir. 2016). Similarly here, ensuring that the price of medicine is fair and reasonable—and not artificially inflated through the unlawful exclusion of competitors—is central to the regulatory framework governing payments under government health programs. (Complaint, ¶¶ 30, 131-37, 139, 141, 144). At the very least, knowledge of the fraud and resulting 650% overcharge would have a "natural tendency to influence, or be capable of

influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4); *Escobar*, 136 S. Ct. at 2002; *Campie*, 862 F.3d 890.

Defendants mischaracterize the allegations in the Complaint and assert that Relator solely recites regulations. (MTD, at 23, *citing Knudsen v. Sprint Commc'ns Co.*, No. C13-04476 CRB, 2016 WL 4548924, at *13 (N.D. Cal. Sept. 1, 2016).[7] That is not true. The Complaint's allegations explain why Defendants' misrepresentations were a necessary prerequisite for Zytiga to be eligible for payment from certain government health programs. The Complaint also alleges that Defendants' fraud would be particularly material to the government, because 80% of Zytiga prescriptions are paid through Medicare, and 90% of the Zytiga prescriptions would have been substituted for a lower-priced generic. (Complaint, ¶ 3) The government has expressed a strong interest in encouraging generic substitution to lower costs.[8]

Defendants suggest their misrepresentations to the USPTO are not material because the government has continued to pay Zytiga invoices even though the '438 Patent has been invalidated. (MTD, 24). That makes no sense. The proceedings invaliding the '438 Patent did *not* address any allegations of fraud. Defendants' argument is also inconsistent with Ninth Circuit law. See *Campie*, 862 F.3d at 905-06 (fraud was material under *Escobar* even if the government continued to pay after knowing of violations of FDA procedures).

Defendants also claim that *Escobar* "rejects" *per se* materiality. This is also incorrect. For example, in *United States v. Berkeley Heartlab, Inc.*, No. CV 9:14-230-RMG, 2017 WL 6015574, at *2 (D.S.C. Dec. 4, 2017) the Court noted that failure to comply with the anti-kickback statute, 42 U.S.C. 1320a-7b ("AKS") "was *per se* material even before [Congress amended the FCA in 2010 confirming it]." The court reasoned that no "reasonable person could believe that AKS compliance is unimportant to the Government's reimbursement decisions" because violation of the AKS "is not a *de minimis* regulatory violation, nor is it a mere technical violation." *Id.*, at *2. The same can be said here. Indeed, Defendants'

[7] Defendants reliance on *Knudsen* is misplaced. The *Knudsen* plaintiff failed to allege the government had even entered into any of the purported contracts. In any event, *Knudsen* did not have the benefit of the Ninth Circuit's views on pleading materiality in *Campie*, the First Circuit's decision on remand in *Escobar*, or the decision in *Heartlab*, 2017 WL 6015574.

[8] The Office of Inspector General of the DHHS has noted that the Centers for Medicare and Medicaid Services "strongly encourages the dispensing of generic drugs." *Generic Drug Utilization in State Medicaid Programs* (July 2006), at iv, available at https://oig.hhs.gov/oei/reports/oei-05-05-00360.pdf.

misconduct would also violate antitrust laws, and the government routinely punishes such misconduct.[9] *See, e.g., FTC v. AbbVie Inc.,* No. 14-5151, 2018 U.S. Dist. LEXIS 109628 (E.D. Pa. June 29, 2018).

It is also beyond dispute that the price of a product purchased by the government is a material term "about the goods." See *Escobar*, 136 S. Ct. at 2001. Under hornbook principles of contract law, price is a quintessential material term. J. D. Calamari & J.M. Perillo, *The Law of Contracts*, § 2-13, at 43-44 & n. 17 (2d ed. 1977); see *Unihan Corp. v. Max Group Corp*., 2011 WL 6814044, at *7 (C.D. Cal. 2011) (price of a product is a material contractual term). In fact, the "centrality" of fair and reasonable drug prices paid by the government confirms that not overpaying for drugs is "'sufficiently important to influence the behavior' of the government in deciding whether to pay the claims." *See Escobar*, 842 F.3d 103, 111 (1st Cir. 2016). The jury can reasonably conclude that knowledge of the fraud and resulting 650% overcharge would have a "natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4); *See Escobar*, 136 S. Ct. at 2002; *Campie*, 862 F.3d at 904-05. *See also*, *U.S.* ex rel. *Grubea v. Rosicki, Rosicki & Assocs., P.C.*, 318 F. Supp. 3d 680, 701 (S.D.N.Y. 2018) (misstatement of information that directly influences the amount the government pays is material); *United States v. DynCorp Int'l, LLC*, 253 F. Supp. 3d 89, 102 (D.D.C. 2017) (defendant's claimed costs "were significantly higher than reasonable, so those claims satisfy *Escobar's* materiality standard").

Defendants misdirect when they assert that there are remedies under patent law, antitrust law or regulatory procedures for challenging pharmaceutical patents or other practices which prevent price competition and the lower prices that necessarily result. (MTD, at 24) The fact that market participants may challenge such illegal activity does not immunize Defendants under the FCA. Defendants cite no authority for this novel contention. Moreover, with respect to claims of fraud, this argument misses the point. Claims of *fraud* on the USPTO cannot be raised in an IPR. (35 U.S.C. § 311(b)). Under Defendants' logic, it is permissible to lie to the USPTO to keep out generics without facing liability other than the loss

[9] Defendants say that Relator must allege, for example, that the government stops paying claims or reimbursing parties "in the mine run of" cases where a pharmaceutical patent is under challenge. (MTD, at 24, *citing Escobar*, 136 S. Ct. at 2002–03) The Supreme Court in *Escboar* provided this *example*, but emphasized that sufficient allegations are "not necessarily limited" to them. *See* 136 S. Ct. at 2003; *see also U.S.* ex rel. *Prather v. Brookdale Senior Living Cmtys., Inc.*, 892 F.3d 822, 834 (6th Cir. 2018) (relator is "not required to make allegations regarding past government action").

of the patent—despite successfully using that fraudulently-acquired patent to obtain several years of monopoly pricing. As the Complaint alleges, Defendants misused the procedures under the Hatch-Waxman Act to secure an automatic 30-month stay blocking generic entry while patent infringement actions were litigated. (Complaint, ¶ ¶ 90-94) Such misconduct was *part* of Defendants' fraudulent scheme.

5. Relator Sufficiently Pleads Scienter

Defendants assert that the Complaint fails to allege that J&J either "knew that its statements were false, or that it was deliberately indifferent to or acted with reckless disregard of the truth of the statements." (MTD, at 25) That is incorrect. The Complaint specifically alleges that J&J intentionally used a patent that it knew was invalid and fraudulently procured to exclude competitors and artificially inflate or maintain the price of Zytiga 650% over what a competitive price would have been. (Complaint,¶ 4). Indeed, Defendants concede in their motion to transfer that the June 2013 submission to the PTO was made from J&J headquarters from a J&J attorney; that the "fair and reasonable" certifications were made by a J&J servicing entity; that the assignee of the patent was a wholly-owned subsidiary of J&J. (Defendants' Motion to Transfer Venue, Dkt. 30, pp. 6-7) And as the courts have made clear, the misconduct of individual applicants for the '438 Patent, and the J&J attorneys prosecuting the patent, are imputed onto J&J. *Avid Identification Sys., Inc. v. Crystal Import Corp.*, 603 F.3d 967, 975 (Fed. Cir. 2010); *Beco Dairy Automation, Inc. v. Glob. Tech Sys., Inc.*, 104 F. Supp. 3d 1023, 1036 (E.D. Cal. 2015) ("an individual's actions may be imputed to a corporate patent owner"). More generally, outside of patent infringement actions, principals are generally liable for the fraud committed by their agents. *Competitive Techs. v. Fujitsu Ltd.*, 286 F. Supp. 2d 1118, 1149 (N.D. Cal. 2003) (patent infringement action stating that a patent assignee "may be held liable [for fraud] on the basis that [the exclusive licensee of the patent] was acting as its agent in the licensing negotiations"); *See Am. Soc'y of Mech. Eng'rs v. Hydrolevel Corp.*, 456 U.S. 556, 566, 102 S. Ct. 1935, 1942 (1982) ("a principal is liable for an agent's fraud though the agent acts solely to benefit himself, if the agent acts with apparent authority")).

6. Relator Adequately Pleads the Submission of False Claims

Defendants claim that Relator has failed to adequately plead the submission of a false claim. (MTD, at 14). Defendants mistakenly rely on *Ebeid* ex rel. *U.S. v. Lungwitz*, 616 F.3d 993, 999 (9th Cir. 2010). In *Ebeid*, the relator failed to plead *any* facts sufficient to show the unlawful practice of medicine or Stark Act violations upon which the false claim was based. Nevertheless, *Ebeid* confirms the sufficiency of the Relator's allegations. Under *Ebeid*, a relator needs only to plead "particular details of a scheme" with "reliable indicia that lead to a strong inference" that claims have been submitted. *Id.* Relator's allegations meet this test. The Complaint alleges that in 2015 and during the first four months of 2017, Medicare and Medicaid alone reimbursed over 80,000 prescriptions of Zytiga for over $650 million. (Complaint, ¶¶ 11-13) The Complaint also alleges that every one of these claims were false. *See generally,* Section III(A)(1).

a. Relator Adequately Pleads a False Statement or Fraudulent Course of Conduct That Caused the Government to Pay Money

Defendants argue, without citing to any authority, that the Complaint's allegations concerning false statements to the USPTO and to the GSA (concerning "fair and reasonable pricing") are not "false claims" actionable under the FCA because they are not misrepresentations on the claim for payment. (MTD, at 15). This has been squarely rejected by the Ninth Circuit.

The FCA does not require that a defendant make a specific misrepresentation in the actual claim itself. Indeed, the Supreme Court and the Ninth Circuit found claims sufficiently pleaded in *Escobar* and *Campie* without such an allegation. This is consistent with well-established precedent in the Ninth Circuit finding sufficient allegations describing "a false statement or fraudulent course of conduct" that causes "the government to pay out money or forfeit moneys due." *Campie*, 862 F.3d at 899. So long as a defendant's false statements are an essential part of a causal chain leading to payment, Defendants are liable under the FCA. *Campie,* 862 F.3d at 903 (collecting cases). *See also Hendow*, 461 F.3d at 1174.

Defendants' argument also confuses proximate causation principles with "implied certification" or "promissory fraud" claims under the FCA. To the extent Defendants argue that the facts pleaded lack a sufficient nexus to a false claim because the causal chain is too attenuated—which is not true—that issue should be resolved by a trier of fact. *See United States v. Celgene Corp.*, 226 F. Supp. 3d 1032, 1049-50 (C.D. Cal. 2016); *cf. Campie,* 862 F.3d at 907. Defendants are liable if the steps in the causal chain are "reasonably foreseeable," and there is no superseding event. *See id*; *see also Hendow*, 461 F.3d at 1174 ("the

precise logistical details of how the claim is made—with respect to timing, for instance, or the number of stages involved—are immaterial: . . . for there to exist a 'claim' for purposes of FCA liability, it must involve merely some sort of request for the government to pay out money or forfeit moneys due.")

Defendants cite to an unpublished, out-of-circuit decision from 2004 called *U.S. ex rel. Promega Corp. v. Hoffman–La Roche, Inc.,* Civil Action No. 03–1447–A (E.D. Va. Sep 29, 2004). (MTD, at 16) Their reliance is misplaced. The Ninth Circuit has explicitly rejected *Promega's* reasoning that there was a "disconnect" between the invoices and the misrepresentations. *Campie*, 862 F.3d at 903. *Promega* was also decided before the 2010 amendments to the FCA, and its dismissal based on the public disclosure bar is no longer good law. Relator also notes that Va. Sup. Ct. R. 5A-1 provides that the decision is not binding authority, and the court has removed the decision from PACER.

Defendants assert that Relator fails to allege an *express* misrepresentation by failing to identify the specific certification or other legal requirement that was violated. (MTD, at 16) This is incorrect. The Complaint adequately pleads the specific certifications. (Complaint, ¶¶ 105-108). Defendants also argue that the Complaint fails to allege an implied false claim because it has not (1) made or caused to be made any specific representations concerning Zytiga, which (2) were misleading half-truths. (MTD, at 17, *citing Escobar*, 136 S. Ct. at 2000-01) The Complaint alleges that every claim for payment relating to Zytiga incorporates an unlawfully inflated price and is a false claim under the FCA. (*Id.*, at 9, 94-98, 102). Defendants also made false or misleading representations that: (a) Zytiga's pricing was "fair and reasonable" to the GSA (Complaint, ¶ 104-111); (b) Zytiga was protected by a valid patent to the FDA (Complaint, ¶ 83); and (c) Zytiga is a drug entitled to patent protection to the USPTO (Complaint, ¶ 75). *See generally,* Sections II(A)-(C) & III(A)(3), *supra*.

b. Relator Adequately Pleads False Statements in Connection With Zytiga's Listing on the Federal Supply Schedule

Defendants contend that their false express and implied misrepresentations that Zytiga pricing was "fair and reasonable" are not false statements because they were not set forth on the invoices submitted but instead were made to "the GSA to obtain listing on the [Federal Supply Schedule]" (MTD, 5). This is wrong. The Ninth Circuit has held that a false statement need not be made in a claim for payment or directly to the paying agency. *Campie*, 862 F.3d at 903; *Hendow*, 461 F.3d at 1174.

Defendants assert that Relator's claim invites a "freewheeling inquiry" into the subjective fairness of a drug's price. (MTD, at 18). Not so. "Fair and reasonable" price is a straightforward concept under the Federal Acquisition Regulations. The basic premise is that prices are set based on competition. As the applicable regulations set forth, the premise of requiring such data is the assumption that "adequate competition" for commercial items sold within a competitive market is a proxy for "fair and reasonable" prices. *See, e.g.,* 48 C.F.R. § 15.402(a)(2) (providing that in "establishing the reasonableness of the offered prices," a purchasing officer need not obtain "certified cost and pricing data as necessary to establish a fair and reasonable price" only if "the price is based on adequate price competition . . . ."); *see generally* § II.A, *supra*. Defendants' proposed construction—that "fair and reasonable prices" refers only to a comparison of prices charged to other customers, regardless of whether such price has been manipulated through anticompetitive or other unlawful, conduct makes no sense. It would disregard the requirement that such prices are only meaningful if there is "adequate price competition." *See also*, *Grubea*, 318 F. Supp. 3d at, 701 (misstatement of the Average Market Price constitutes an FCA violation; and because such misstatement influences the amount the government pays, is material); *cf. DynCorp*, 253 F. Supp. 3d at 102 (reporting costs that are "significantly higher than reasonable" are material FCA violations).

Relator's theory of promissory fraud is well-established and non-controversial. *See U.S.* ex. rel. *Dresser v. Qualium Corp.*, No. 5:12-CV-01745-BLF, 2016 WL 3880763, at *5 (N.D. Cal. July 18, 2016) ("promissory fraud . . . holds that liability will attach to each claim submitted to the government under a contract, when the contract or extension of government benefit was originally obtained through false statements or fraudulent conduct") (*citing Hendow*, 461 F.3d at 1173). *See also Campie,* 862 F.3d at 902.

With respect to Relator's "promissory fraud" or "fraudulent inducement" theory, Defendants attempt to draw a distinction between a "condition of participation" and a "conditions of payment," saying that the former does not support FCA liability. (MTD, at 19)[10] Here, as in *Escobar*, *Campie,* and *Hendow*, Relator alleges that Defendants would *not* have received payment from certain government health funds but for its false representations that the prices of Zytiga were fair and reasonable.

[10] *United States v. N. Am. Health Care, Inc.*, 2015 WL 6871781 (N.D. Cal. Nov. 9, 2015) is inapposite because the inflated quality ratings at issue were not tied to payment or a statutory requirement.

(Complaint, ¶ 112); *see United States v. Ctr. for Employment Training*, No. 213-CV-01697, 2016 WL 4210052, at *7 (E.D. Cal. Aug. 9, 2016) ("the distinction between a condition of participation and a condition of payment is one without a difference. . . . If conditions of participation were not conditions of payment, there would be no conditions of payment at all.") (citation omitted).

Defendants argue that an FCA claim does not lie where payment is "not conditioned on perfect regulatory compliance—and where [an agency] may choose to waive administrative remedies, or impose a less drastic sanction than full denial of payment." (MTD, at 20, *citing U.S. ex rel. Swan v. Covenant Care, Inc.*, 279 F. Supp. 2d 1212, 1222 (E.D. Cal. 2002)). *Swan* does not apply. The requirements for payments or reimbursement for Zytiga are nondiscretionary. Fraud on a government agency is not a simple matter of waivable regulatory compliance.

As *Campie* explained, a false statement is material and supports FCA liability if it has "a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Campie*, 862 F.3d at 904-05. Both *Swan* and *N. Am. Health* were decided before *Escobar* and *Campie.* Thus, the relator in *Campie* pleaded a viable FCA claim for "promissory fraud" or "fraudulent inducement" even if the FDA could technically have "waived" Gilead's non-compliance with FDA regulations. To the extent that *Swan* and *N. Am. Health* hold otherwise, they have been overruled by *Campie*, 862 F.3d at 902.

Finally, Defendants' hyperbole that Relator's theory of falsity is "shockingly broad" is misplaced. Relator does not contend that an FCA violation exists merely because a patent challenged in an IPR, or even that a patent is found to be invalid. Rather, FCA liability exists where, as here, there are particularized allegations that Defendants obtained a patent through conduct that would satisfy common-law standards for fraud, and the government has overpaid hundreds of millions of dollars as a result. *See Escobar,* 136 S. Ct. at 1999 (FCA violations are determined under common law principles).

c. The Heightened Standard for Pleading an "Inequitable Conduct" Affirmative Defense for Patent Infringement Does Not Apply Here

Defendants say that Relator must plead Defendants engaged in inequitable conduct with respect to the portions of Defendants' misrepresentations addressed to the USPTO. Defendants cite *Avid*, 603 F.3d at 974 n.1; and *MONKEYmedia, Inc. v. Twentieth Century Fox Home Entm't., LLC*, 242 F. Supp. 3d 551, 554 (W.D. Tex. 2017). (MTD, at 20) Both of those cases are patent infringement suits where inequitable

conduct was raised as an affirmative defense to a patent infringement claim. Defendants cite to no authority holding that the standard for inequitable conduct applies to the FCA. It does not.

In *Escobar,* the Supreme Court explicitly held that determining a false or fraudulent statement under the FCA requires the application of common law standards. *Escobar,* 136 S. Ct. at 1999. Inequitable conduct is an affirmative defense against a patent infringement claim. Defendants provide no reason why it should be imported into the FCA, contrary to *Escobar*.[11]

Even if the heightened standards for inequitable conduct applied, the Complaint alleges with particularity that Defendants intentionally withheld information concerning FDA approvals that they knew were material to fairly comparing market share data, or the presence of blocking patents and other factors that explained commercial success unrelated to the claimed invention. (Complaint, ¶¶ 75-80). Such allegations easily demonstrate a "deliberately planned and carefully executed scheme" to fraudulently obtain a patent for the purpose of excluding competitors and artificially raising or maintaining prices for Zytiga. *See Therasense*, 649 F.3d at 1290 (internal citations omitted); *see also Revolution Eyewear, Inc. v. Aspex Eyewear, Inc.*, 2005 WL 8156817, at *3 (C.D. Cal. May 2, 2005) (false statements concerning commercial success was "clear and convincing evidence of inequitable conduct").

Although not necessary, Relator also sufficiently pleads "but-for" materiality as a matter of patent law. For withheld information to be deemed material for inequitable conduct, the information must not be cumulative of information on record with the USPTO, and it must either establish a *prima facie* case of unpatentability of a claim; or refute, or be inconsistent with, a position asserted to obtain a patent. *See Purdue Pharma, L.P. v. Endo Pharms. Inc.*, 438 F.3d 1123 (Fed.Cir.2006) (*quoting* 37 C.F.R. § 1.56(a)). The Complaint here alleges with specificity that the '340 Application had been rejected numerous times by the USPTO (Complaint, ¶ 68); that the patent examiner specifically instructed Defendants to provide relative

[11] In *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 288-89 (Fed. Cir. 2011), the Federal Circuit raised the requirements for proving inequitable conduct (for example, requiring a specific intent to deceive and but-for materiality) based on the court's view that assertion of an inequitable conduct defense to an infringement suit has the effect of an "atomic bomb" that can "endanger a substantial portion of a company's patent portfolio," including continuation and divisional patents, even if those other patents are untainted by the inequitable conduct. The rationale for the higher standard for inequitable conduct is inapplicable to FCA claims, which must be "broadly construed" to "reach all types of fraud, without qualification, that might result in financial loss to the Government." *Hendow*, 461 F.3d at 1171; *Campie*, 862 F.3d at 899.

market share comparisons if they wished to demonstrate "commercial success" necessary to have the patent issued (Complaint, ¶ 73); and that Defendants' false and misleading statements in the June 2013 submission in response to the examiner's instructions was the "but-for" cause for the issuance of the '438 Patent (Complaint, ¶¶ 78-79). Defendants make no attempt to argue the withheld market information was cumulative to what had been disclosed to the USPTO. In fact, it was contrary to what was disclosed.

Finally, Defendants say that the inequitable conduct doctrine imposes the duty of "candor and good faith" on individuals filing documents with the USPTO, and not to corporations. Defendants further assert that the Complaint does not identify the individuals whose obligations of "candor and good faith" are imputed to the patent owner. (MTD, 21) But Defendants' RJN clearly identifies one of the inventor-applicant's as Alan H. Auerbach. (RJN, Ex. B) He is the Founder, Chief Executive Officer, President, and Director of defendant Janssen Oncology (formerly, Cougar Biotechnology). (Dkt. 35, at 6-7) A reasonable inference based on Mr. Auerbach's position is that he knew full well the FDA approval status of Zytiga's principal competitor; that Zytiga was protected by a blocking patent; and that the reasons for Zytiga's supposed commercial success had nothing to do with what Defendants claimed to the examiner. Additionally, Andrea Kamage, J&J's patent counsel identified in RJN Ex. C, at p. 61 of 64, authorized the filing of the June 2013 submission. In their motion to transfer papers, Defendants referred to Ms. Kamage as a "key witness" concerning the prosecution of the '438 Patent. (Dkt. 37, at 7)

In *Avid*, 603 F.3d at 973-74 & n.1, cited by Defendants, the Court clarified that the conduct of applicant is "imputed" onto the corporate assignee of the patent. The court held that an individual's failure "to comply with his duty of candor" is "chargeable to the applicant for the patent" and therefore, the conduct of Avid's president was properly "imputed" to the company. *Id.* This is why inequitable conduct is almost universally asserted against the corporate owner of patent.

It is true that when inequitable conduct is asserted as an affirmative defense to a patent infringement action, courts apply a heightened pleading standard with respect to the identity and knowledge of specific individuals materially participating in the patent prosecution. *See Breville Pty Ltd. v. Storebound LLC*, No. 12-CV-01783-JST, 2013 WL 1758742, at *5 (N.D. Cal. Apr. 24, 2013). This is not a patent infringement action, and nobody has asserted inequitable conduct as an affirmative defense. The

Supreme Court instructs that allegations of falsity under the FCA must to be judged according to common law standards under ordinary Rule 9(b) principles. *Escobar,* 136 S. Ct. at 1999. Because Defendants have exclusive knowledge who they internally assigned to prosecute the '438 Patent (other than Mr. Auerbach and Ms. Kamage, which are identified in the documents to which the Complaint refers and which Defendants ask the Court to take judicial notice), the Ninth Circuit applies a relaxed Rule 9(b) pleading standard to Relator's allegations in the Complaint. *Breville*, 2013 WL 1758742.

The Complaint alleges that Defendants, as the real parties-in-interest of the Patent, obtained the '438 Patent through fraud. They did so through filings submitted by their attorneys, executives, and employees, all of whom indubitably had obligations of candor and good faith when prosecuting the '438 Patent on behalf of their corporate principals. Defendants cannot escape liability by hiding behind their agents. *See Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 & n.1 (Fed. Cir. 1995).

B. There Has Been No Public Disclosure of Defendants' Fraud

The public disclosure bar is limited, particularly after the 2010 amendments. The FCA bars *qui tam* actions only if the material allegations of fraud were disclosed in: (i) a federal criminal, civil, or administrative hearing or proceeding "in which the Government or agent is a party"; (ii) a Congressional or federal report, hearing, audit or investigation; or (iii) the news media. 31 U.S.C. § 3730(e)(4)(A).[12]

Congress amended the public disclosure bar in 2010 to allow this type of *qui tam* action. *See* § III.A.1, *supra*. In contrast, "parasitic" suits barred by the FCA are typified by those cases where individuals would merely copy allegations of fraud of existing government investigations reported in newspapers to receive a cut of the relator's bounty, *see* H.R. Rep. 102-837 (1992), at 12.[13]

Defendants' reliance on *Amphastar*—a pre-2010 FCA case—is misplaced. In *Amphastar*, the relator alleged that the defendants fraudulently obtained a pharmaceutical patent and used it to block generic entry, thereby inflating the price charged for the drug. The court held that these allegations stated

[12] The 2010 amendments to the FCA converted the public disclosure bar from a jurisdictional bar to an affirmative defense governed under Rule 8. *Prather v. AT&T, Inc.*, 847 F.3d 1097, 1102 (9th Cir.) As such, Defendants' arguments based on public disclosure are not proper under Rule 12(b), because their resolution relies on facts outside the complaint. *Sams v. Yahoo! Inc.*, 713 F.3d 1175, 1179 (9th Cir. 2013).

[13] Defendants charge that this *qui tam* is a "parasitic" lawsuit. (MTD, 6) The opposite is true. In its 2010 amendments to the FCA, Congress confirmed that it did not consider suits such as Relator's to be parasitic, but instead an important tool to fight healthcare fraud H.R. Rep. 102-837 (1992), at 12.

valid claims under the FCA. *See Amphastar Pharms. Inc. v. Aventis Pharma SA*, No. EDCV-09-0023-MJG, 2012 WL 5512466, at **9-12 (C.D. Cal. Nov. 14, 2012); No. 5:09-cv-00023, Dkt. 110 (holding that every claim that included an inflated price was a false claim because such prices implied a "patented brand-name drug" was being billed when in fact the drug was actually for a "non-patented drug").

Subsequently, after determining that relator's claims were disclosed in prior infringement actions (which qualified as public disclosures prior to the 2010 amendments), the court vacated its prior orders on jurisdictional grounds.[14] The Ninth Circuit affirmed dismissal on those grounds, without addressing the sufficiency of the fraud allegations. Had *Amphastar* been filed after the 2010 amendments became effective, any disclosures in the patent infringement actions would not have barred the action, because the government was not a party to them. *See* § 3730(e)(4)(A)(i).[15]

1. Defendants Rely on Disclosures Excluded by the FCA[16]

a. The IPR Filings Upon Which Defendants Rely Do Not Establish "Public Disclosure" Sufficient to Bar Relator's Claims Under the FCA

Defendants claim that IPR petitions filed by Amerigen, Wockhardt, and Mylan disclosed some of the reasons the '438 Patent is invalid. (MTD, at 7, *citing* RJN Exs. D-F) Defendants also say that two news articles and certain SEC filings by J&J disclosed the existence of the IPRs (but did not include details about their contents). (*Id.*, *citing* RJN Exs. K-N, P, Q) There are four critical flaws with this argument.

First, an IPR is not one of the specified ways a fraud may be publicly disclosed under the FCA. It is an "administrative proceedings" under 31 U.S.C. § 3730(e)(4)(A)(i), but the government is not a party to them. Here, the IPR petitions confirm that the government was not a party. (RJN, Exs. D-F).

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[14] The court noted that its prior decisions had been questioned in a law review article. *Id.* at *1 & n. 5. That article was written by a law student and two associates at defense firms, one of whom (Mr. Avery) represented pharmaceutical companies in patent prosecution. Notably, the cited article concedes that the courts' broad interpretation of the FCA over the years has "made claims like Amphastar's feasible." Gregory Michael, *et al.*, *The New Plague: False Claims Liability Based on Inequitable Conduct During Patent Prosecution*, 25 Fordham Intell. Prop. Media & Ent. L.J. 747, 784 (2015).

[15] Confusingly, Defendants also assert that the public disclosure bar applies if a "critical mass" of allegations have been disclosed. (MTD, 6, *citing Amphastar*, 856 F.3d at 703) This requires a weighing of the evidence and a factual inquiry not appropriate for an attack on the pleadings under Rule 12.

[16] Defendants rely on documents for which they ask the court to take judicial notice. The Court should not take judicial notice of RJN Exs. A through HH for the purpose of establishing what Relator or the general public "knew about the status" of Zytiga's commercial success or efficacy compared with competing treatments. *See, e.g., Khoja v. Orexigen Therapeutics, Inc.,* 899 F.3d 988, 1000 (9th Cir. 2018).

Second, the news articles and SEC filings that Defendants cite do not disclose any material allegations of fraud.[17] They only report the names and docket numbers of the IPRs, not their contents.

Third, the IPRs did not disclose or litigate the *fraud* alleged in this suit. Other than generally refuting Defendants' analysis of the nexus between the '340 Application's claimed invention and Zytiga's successful market share performance, the IPRs do not allege fraud. This is not unsurprising because the PTAB does not have jurisdiction to invalidate a patent based on fraud or inequitable conduct. (35 U.S.C. § 311(b)). The IPRs invalidated the '438 Patent, but they contained no findings the patent was fraudulent.

Fourth, none of the purported public disclosures relied upon by Defendants disclose the most important allegation of fraud in the Complaint: Defendants failed to disclose that Zytiga's principal competitor for chemo-naïve patients (Xtandi) had not obtained FDA approval for that indication. (*Compare,* Complaint, ¶¶ 77(a)-(d) with RJN Exs. D-F) Conceding this point, Defendants assert that the IPR petitions vaguely challenged the "data as 'deficient' and contended that Zytiga's commercial success was in fact less robust." (MTD, at 8, citing RJN Exs. D & E). While this may be so, this is not the fraud Relator asserts. The Complaint specifically alleges that Defendants told the PTO that Zytiga gained market share against Xtandi, thereby misrepresenting and omitting that the reason for the commercial success (gain in market share) was because Xtandi had not received FDA approval.

b. The Filings Contained in the '438 Patent Prosecution Docket Do Not Establish "Public Disclosure" Sufficient to Bar Relator's Claims

Defendants also claim that Relator's allegations were publicly disclosed on the USPTO's Patent Application Information Retrieval ("PAIR") docket system. (MTD, 10) This is misguided.

First, like IPR proceedings before the PTAB, patent prosecution proceedings before the USPTO do not constitute a qualifying public forum under the FCA. A patent prosecution proceeding before the USPTO is an administrative proceeding where the government is not a party. *See* § 3730(e)(4)(A)(i).

[17] At most, the news articles and SEC reports merely disclose the *existence* of the IPRs, without describing their contents or linking to them. The news articles lack the requisite level of specific, granular details sufficient to alert the government of fraud. *Mateski*, 816 F.3d at 577.

Defendants reliance on *U.S.* ex rel. *Proctor v. Safeway, Inc.*, No. 11-cv-3406, 2016 WL 7017231, at *12 (C.D. Ill. Dec. 1, 2016) is misplaced. *Proctor* is of no precedential value because it does not explain what materials regarding the lawsuit, or which material in the court file, constituted public disclosure. Moreover, *Proctor* denied the motion to dismiss, holding that there had been no public disclosure.

Second, the PAIR docket is not a "federal report." As the Ninth Circuit has held, "reports and investigations generally involve independent product" including "analysis of findings" or "governmental leg-work." *U.S.* ex rel. *Haight v. Catholic Healthcare W.,* 445 F.3d 1147, 1153 (9th Cir. 2006), *abrogated on other grounds, Schindler Elevator Corp. v. U.S.* ex rel. *Kirk*, 563 U.S. 401, 407-08 (2011). PAIR discloses only limited information, and does not include governmental findings, analysis, or leg-work .[18]

Third, the PAIR docket is not "news media" simply because it is available on the internet. (MTD, at 9-10, *citing Hong*, 2016 WL 8929246, at *5). PAIR is like PACER, which discloses criminal and civil litigation documents to which the government is not a party, and which indisputably *not* a public forum under the FCA. If Defendants' argument were accepted, then judicial expansion of the "news media" category would effectively nullify the specific exemptions Congress enacted in 2010. Also, PAIR can only be accessed after logging into the system and entering queries for documents; they are not searchable through Google or other browsers; and they are not curated. *See Liotine v. CDW Gov't, Inc.*, 2009 WL 3156704, at *6 & n. 5 (S.D. Ill. Sept. 29, 2009) (website not an FCA specified public forum because it required users to take several steps to locate information).

Fourth, there is no public disclosure of the material allegations of fraud on PAIR. Defendants confusingly claim they could not have told the USPTO in June 2013 that Xtandi would be approved for chemo-naive patients in September 2014. But Defendants *could* have and *should* have told the USPTO that Xtandi had *not yet been approved* for the chemo-naïve indication when comparing Zytiga's commercial success against Xtandi for the chemo-naïve indication. That is the very essence of the fraud.

Defendants also say that a few reasons for Zytiga's commercial success unrelated to the purportedly inventive claims of the '438 Patent (such as the drug resistance in patents and median survival rates in patients, and the anti-cancer properties of abiraterone acetate), as opposed to co-administration with prednisone, were disclosed in the June 2013 submission. (MTD, at 10-11) But the 2013 submission, disclosed only on PAIR, does not constitute a public disclosure. Further, even if the patent filings

[18] *Schindler,* 563 U.S. 401, provides no support for Defendants' arguments. *Schindler* held that documents produced in FOIA requests are "federal reports" because they require each agency to make an independent determination as to what to include in response). The PAIR docket is not analogous because it does not require synthesis or analysis or provide meaningful insight. *Compare*, *id.*, at 418 (Ginsburg, Breyer, and Sotomayor, *JJ.* dissenting) (FOIA request does not require sufficient analysis to be a report).

mentioned these facts (including a disclosure in the '213 Patent concerning the efficacy of 17α-hydroxylase/$C_{17,20}$-lyase inhibitors in treating cancer) (RJN, Ex. I, at 7, ¶ [0035]), they were not raised in connection with Defendants' claims of commercial success. Defendants cited them for completely different purposes. They did not constitute adequate disclosure to the USPTO as required by Rule 1.56. Regardless, this is a question of fact not properly resolved on a motion to dismiss.

c. The Scientific Literature Does Not Establish "Public Disclosure"

Finally, Defendants argue that facts relating to Zytiga's commercial success that Defendants failed to disclose to the USPTO were disclosed in various scientific articles and elsewhere. (MTD, at 11-12, citing RJN O, G, W, X, Y, and Z) Such facts include the need for second-line therapies, sequencing issues for various drugs, relative toxicity, pricing disparities, and methods of administration. (MTD, 11, *citing* Complaint ¶¶ 80(d), (g)-(h)) Defendants also say that Xtandi's September 2014 approval for chemo-naïve patients was reported by the press. (MTD, 10, citing RJN, Ex. T). Defendants' argument suffers from a critical logical flaw. Assuming, for the sake of argument, that the *real* reasons for Zytiga's commercial success (unrelated to the claimed invention in the '438 Patent) were publicly disclosed, this does not mean that the essential elements of Relator's *fraud allegations* were publicly disclosed. The Complaint alleges that Defendants *should* have but *did not* disclose such reasons for Zytiga's apparent commercial success to the USPTO. That is the crux of Relator's fraud allegations, and that fact was not disclosed in any document upon which Defendants rely.

The underlying premise for imposing a duty of candor and good faith on patent applicants is that the government cannot be deemed to possess knowledge of every scientific study or prior patent that may relate to an application. Particularly for FCA claims based on patent fraud, it makes no sense to attribute near-omniscience to the government when determining whether purported public disclosures were "sufficient to enable [the government] adequately to investigate the case and to make a decision whether to prosecute." *U.S.* ex rel. *Found. Aiding the Elderly v. Horizon W.*, 265 F.3d 1011, 1016 (9th Cir. 2001).

2. Defendants Do Not Allege Public Disclosure of the Misrepresented State of Facts

Defendants submit documents showing Zytiga's FSS price, but none of them demonstrate public disclosure that false claims were submitted. (RJN, Exs. GG & HH) That level of generality—without

disclosure of specific, granular details sufficient to alert the government of fraud—is insufficient to establish public disclosure. *Cf. U.S.* ex rel. *Mateski v. Raytheon Co.,* 816 F.3d 565, 577 (9th Cir. 2016) (allowing disclosure of "generalized fraud" to bar FCA suits "would deprive the Government of information that could lead to recovery of misspent Government funds").

C. Relator is an "Original Source" of the Material Allegations of Fraud

Even if there has been a public disclosure in an enumerated forum under 31 U.S.C. § 3730(e)(4)(A)(i)-(iii) of all the material elements constituting fraud—which did not occur—Relator may still pursue his claims if he is an "original source" possessing information that is "independent of and materially adds to" the publicly-disclosed allegations or transactions. *See* 31 U.S.C. § 3730(e)(4)(B).

Defendants' assertion that Relator "repackaged" material that was publicly filed rings hollow. Relator does not simply "repackage" what was disclosed in the IPRs. (MTD, 5) For example, through his particular knowledge and expertise, Relator uncovered Defendants' misleading and nonpublic omission of material facts concerning FDA approval dates for Xtandi. (Complaint, ¶¶ 77(a)-(d)). This is a critical allegation of fraud alleged in the Complaint, and no document that Defendants cite to in their papers disclosed it. The importance of this omission is the subject of proof—likely from experts—and raises a question to be resolved by a jury. Relator is the original source—indeed the only source—of this allegation, and he disclosed it to the government prior to filing suit. (Complaint, ¶ 18).

D. Relator Has Sufficiently Pleaded Claims Under the State Law Causes of Action

Because Relator has adequately pleaded federal FCA claims, the state claims should be upheld.[19]

IV. CONCLUSION

The Court should deny Defendants' motion to dismiss in its entirety. In the alternative, if the Court finds any deficiency in the Complaint, the Court should permit Relator to amend his pleading.

[19] The Texas Attorney General has requested Relator to inform the Court that the Texas causes of action do not require the presentment of a false claim, and most do not require proof of materiality. Tex. Hum. Res. Code §§ 36.002(1)-(13). Therefore, Defendant's arguments do not apply to Texas.

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JOSEPH SAVERI LAW FIRM, INC.

By: */s/ Joseph R. Saveri*
Joseph R. Saveri

Joseph R. Saveri (State Bar No. 130064)
Steven N. Williams (State Bar No. 175489)
Nicomedes Sy Herrera (State Bar No. 275332)
Kevin Rayhill (State Bar No. 267496)
Anupama K. Reddy (State Bar No. 324873)
JOSEPH SAVERI LAW FIRM, INC.
601 California Street, Suite 1000
San Francisco, California 94108
Telephone: (415) 500-6800
Facsimile: (415) 395-9940

Attorneys for Plaintiff-Relator Zachary Silbersher